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Review

Design evolution in total knee replacement: which is the future?

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Abstract. Total knee replacement (TKR) procedures have evolved in the last 40 years to guarantee improvements implants life and an excellent joint function. The goals for the future evolutions are make easier prosthesis implantation and promote precision. The demand for TKR will rise for the life length increase and for the risk factors impact increase. Design evolution in total knee replacement has to satisfy these new necessities: anatomic congruence, range of motion, less material wear and better resistance to the weight bearing and to the stresses. This paper analyzes design evolution, materials development and future purposes in total knee arthroplasty. At the beginning, TKR history is treated; then we compare several prosthetic designs developed during years. At last the paper speak about recent innovations, like CAD (computer aided design) for example, born to reach the most important goal in the future: better TKR design, is the one that better imitate natural knee characteristics, and that is able to integrate it-self with capsule-ligaments and muscle-tendons patient structures. (www.actabiomedica.it)

Key words: total knee artroplasty, design, materials, evolution

Introduction

Total knee replacement (TKR) procedures, evolved in the last 40 years, to guarantee an improvement of implants life and an excellent functionality for the patient and a cost reduction.

The demand for TKR will rise for the life length increase and for patient's weight increase too; moreover, a great number of patient older than 65, nowadays plays sport and pretends a better result than some years ago (1); at last must be considered the increasing of Asiatic demand.

Design evolution in total knee replacement has to satisfy these new necessities: anatomic congruence, articolarity, less material wear and better resistance to the weight and to the stresses, cost reduction.

TKA history

The first models of TKA, born to "imitate", the knee, go back in the XIX century. The first attempt to build an artificial knee was in 1860 with Verneuil: he used articular capsule to recreate the joint. After this first attempt, there were other experiments with Ollier, Murphy and Campbell; they used different materials (like muscle, fat and fascia and pig bladder respectively).

Gluck in 1890 realized the first model of hinge prosthesis probably never implanted. It's very difficult describing TKR design evolution: too many designs in too many years.

The first attempts to create a TKR, as we know it, occurred in the forties; partial prosthesis, only for the femoral part of the joint (2) (Boyd in 1938; Campbell with the first prosthesis in Vitallium in 1940; Cabitza in 1950; Kraft and Levinthal in 1954) or for the tibial one (Burman in 1944; Kiaer in 1963; Macintosh in 1956). Judet in 1947 was the first that tried to recreate a complete joint; modern TKR, was borned.

First models to obtain a marked success and a large diffusion were central (Walldius in 1954) or posterior axis (Shiers in 1954). Among the hinge models subsequently achieved, let's recall the Lagrange e Letournet (1970) with central rotating axis and the Guepar (1971) with totally posterior rotating axis.

The Bousquet-Trillat's prosthesis (1971), represented an evolution of previous hinge designs, displaying rotating movements which could accommodate tibial torsional stresses. Rotating movements were also displayed by Herbert's prosthesis (1972) which was quite different in conception from traditional hinge models.

Since hinge models never respect normal knee kinematics, they found indication only in cases of severe knee capsule-ligament laxity.

Gunston in 1965 was among the first to create a total knee prosthesis following the principle of sliding (polycentric TKA); the prosthesis allowed a limited bone resection and also, the lack of constraints enabled the mecanichal stresses to be absorbed by the joint capsule-ligaments apparatus.

But, with this design the releasing of forces took place in a restricted area of the tibial ephyfisis, at the risk of the implant sinking. Hence, the tendency to construct uniblock bicondylar sliding prosthesis (Paltrinieri Freeman with Swanson, Upshaw and Walker in 1973).

In 1973 was also born Insall's Total condylar prosthesis; Insall and Gunston's models, probably, have been considered the first "modern prosthesis". Insall's design provided PCL sacrifice; stability on sagittal plane, warranted by articular conformation. The design of the total condylar prosthesis included a chrome cobalt femoral component with a symmetrical anterior flange for patellar articulation. The symmetrical femoral condyles had a decreasing sagittal radius of curvature posteriorly and were individually convex in the coronal plane. The double-dished articular surface of the tibial polyethylene component was perfectly congruent with the femoral component in extension and congruent in the coronal plane in flexion. Translation and dislocation of the components were resisted by the anterior and posterior lips of the tibial component and the median eminence. The tibial component had a metaphyseal stem to resist tilting of the prosthesis during asymmetrical loading. The tibial component originally was all-polyethylene, but metal backing was added later to allow more uniform stress transfer to the underlying cancellous metaphyseal bone and to prevent polyethylene deformation. The patella was resurfaced with a dome-shaped, all-polyethylene patellar component with a central fixation lug. Two early criticisms of the total condylar prosthesis were its tendency to subluxate posteriorly in flexion if the flexion gap was not balanced perfectly with the extension gap and a smaller range of flexion compared with prosthetic designs that allowed femoral rollback to occur. By not "rolling back," the posterior femoral metaphysis in a total condylar knee impinged against the tibial articular surface at approximately 95 degrees of flexion. To correct these problems, the Insall-Burstein posterior cruciate–substituting or posterior-stabilized design was developed in 1978 by adding a central cam mechanism to the articular surface geometry of the total condylar prosthesis. The cam on the femoral component engaged a central post on the tibial articular surface at approximately 70 degrees of flexion and caused the contact point of the femoral-tibial articulation to be posteriorly displaced, effecting femoral rollback and allowing further flexion.

Concurrent with the development of the cruciate-sacrificing total condylar prosthesis, the duopatellar prosthesis was developed with the sagittal plane contour of the femoral component being anatomically shaped. This prosthesis (Kinematic Condylar in the 80's) included retention of the posterior cruciate ligament (PCL). Originally, the medial and lateral tibial plateau components were separate, but this was soon revised to a one-piece tibial component with a cutout for PCL retention.

Many of these design characteristics are retained in current designs.

From the on we had very important evolutions in prosthetic design and in the operative techniques for TKR; in fact nowadays TKR is a surgical procedure very effective and easily reproducible for the treatment of knee ostheoarthrosis. It values about 10 millions of TKR for year with an increase of 10% every year (3).

TKA: CR or PS

An overwhelming majority of TKR nowadays are “fixed-bearing” (less “mobile-bearing), divides equally in PCL preservation designs (CR) and PCL substitution designs (PS). Many papers were carried out to evaluate which was the better design to guarantee better results. It wasn’t easy highlighting big differences between this two designs (reliability and duration guarantee during the years, are similar for both the designs) (4). Some authors, the most, prefer CR design (5-8); many papers, in fact shows that PCL retaining, guarantees extensor apparatus strength, agrees conservation of proprioceptivity, consents bone stock preservation with less fracture risk and permits a revision surgery easier. Other authors don’t prefer one of two designs (similar for results and characteristics) (9-13); others prefer substitution design (14, 15).

For some authors PCL retaining isn’t useful for knee cinematic after TKA16·17; they think it’s very difficult to obtain a perfect balance between central pivot and collateral ligaments in CR design (18-20.

Insall, instead, noticed that PS designs were related with patellar pain, malfunction, sub-dislocation and dislocation (21); another paper shows that PS design transmits heavier load on tibial axis with wear increasing (22).

Prosthesis design in which both the cruciates aren’t sacrificed, isn’t frequently used because of balance difficulty between four knee ligaments. Femoral and tibial anatomic congruence in CR design it’s less than PS one; it permits a greater ROM, but also causes a “sliding” and wear stress increasing, and, consequently prosthetic components instability (23). Moreover a major anatomic congruence causes a less variability of knee kinematic with a better stability, but this isn’t sureness of better function of patient neo-joint. In fact notable articular congruence of PS design (on the femoral and on the tibial component), consents a femoral posterior dislocation during hyper-flexion movements, certain a good factor, but consents also an anterior and posterior damage for major wear that, in certain events, evolves in a fracture (24-26). Moreover, femoral resection necessary to create a femoral housing, can become a problem for smaller knee. At last, both CR and PS, there’s, besides tibial wear, posterior wear between tibial bearing and metal; this is a problem in case of insufficient prosthesis locking (27).

TKA: cementeted or cementless

Development of Porous coated design, was based on the use of polyethylene pegs to avoid cement; for some authors this was an option to increase implant-life. Freeman, Hungerford, Kenna and Krachow were the firsts to develop this idea (28-30). Many papers have been done to evaluate which was the best design between this two models. One of these (31), analized results obtained on 143 pazients; in some of these patients were implanted a How-Medica Porous–Coated prosthesys; in the others a cemented design (Howmedica Kinematic II). The results highlighted a better knee articularity in cemented design (106° against 97° average of ROM); a major pain incidence and the need to using crutches for an higher lapse of time in porous coated design. The important factor in this, and in other papers (32, 33), was the rating of re-intervention, particularly because of tibial component loosening (12% of patients with porous coated design against 4% of complication, no-one for loosening, in cemented design). In time, improving of cemented TKA, reduced the use of porous coated prosthetic design.

TKA: symmetrical or asymmetrical

There’s another subdivision in fixed-bearing prosthesis: symmetrical TKA (Total Condilar, Johnson & Johnson or Insall-Burnstein posterior stabilized knee, for example) and asymmetrical TKR (PCA Howmedica for example). Symmetrical TKAs were born to reduce problems like patellar bad-sliding on trochlear groove or post-operative pain and to improve patients articularity. An example was Kinemax plus (Howmedica), a symmetrical prostheis, evolution of Kinematic, an asymmetrical prosthesis; many papers compare this two different designs (34, 35). Symmetrical TKA, has a design with a trochlear groove parallel to knee flexion-estension axis, and deeper to increase patellar-prosthesis congruence (Fig. 1).

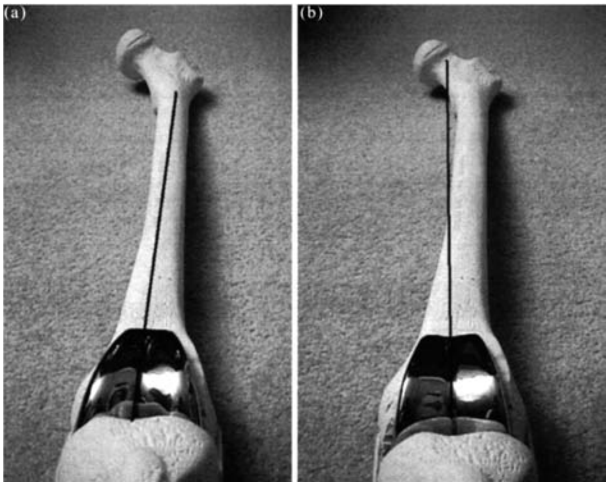

Figure 1. T. Ashraf*, D.J. Beard, J.H. Newman Symmetrical vs. asymmetrical total knee replacement—a medium term comparative analysis The Knee 10 (2003) 61–66

An asymmetrical TKA has a throclear groove aligned with femur longitudinal axis.

These two characteristics consent, patellar tilt and sub-dislocation prevention, wear and patellar fracture reduction (36-39). Same papers showed similar values in post-operating ROM, with a less complications incidence for symmetrical design. Post-operative pain was a recurrent factor in asymmetrical models, probably because of femoral component medial contour, that causes a capsular impingement with patellar pain and "clicking".

TKA: mobile or fixed-bearing

In the 70's have been introduced "mobile-bearing" designs; their goals were to increase contact area between femur and tibia, to reduce load and polyethylene wear; other targets was to reduce dislocation strengths on bone/prosthesis interface and to permit a better movement freedom. At last they'd have permitted to surgeon a sort of "error margin" and in the meantime they'd have consented an improvement of implant functionality (40). Some papers confirmed for mobile –bearing design a wear reduction (41); clinic comparisons showed, instead, an important wear on tibia-bearing interface (42, 43) called back-side wear, probably because of a less lubrification with sub-micron particle production [other papers (44, 45), don't confirm this results; they indeed, show a major osteolisys in fixed-bearing design]; the mobility on the femur/bearing interface, instead, consent a less wear with a consequent reduction of loosening (46, 47). This theory too, is not confirmed by many papers (48-50). Moreover mobile bearing design could consent a better kinematic and a better "rotational mistakes" tolerance during operating procedure. Many papers, however, don't confirm a ROM improvement (51) or a less rotational mistakes incidence (52). A limit of mobile-bearing design are bearing loosening; this design, in fact, need a better ligament balance. Many papers show a loosening incidence about 1-9% (53, 54); loosenings are associated with popliteal thrombosis (55, 56) and pseudoaneurisms (57, 58).

Mobile-bearing finds indications in young patients, but a recent paper (13 years follow-up) show osteolysis rate (1,6 and 2,2% in fixed and mobile-bearing) and revisions rate (3,7% and 2,7% respectively) similar between two designs (59). A sure advantage in mobile-bearings is less rate of lateral-release during procedures. A retrospective paper (carried out on 1300 patients) (60) shows a lateral-release rate of 14,3% in fixed-bearing designs vs 5,3% in fixed-bearing ones.

Finally in mobile-bearing design there is a less patellar wear (61).

Survival of this two models and patient's agreement is similar (62-64).

Materials

Nowadays, engineers are trying to create and to develop new materials, to reduce bearing wear and to increase prosthesis resistance to the stresses. New highly cross-linked polyethylene, is a new material, born to reduce to a minimum free radical production and to optimize oxidation resistance. Many papers, demonstrated that this new material, reduce wear in comparison with earlier polyethylenes (65-68). This factor consents to research new design not as much to reduce wear but to recreate the normal knee anatomy.

All-tibial polyethylene design, was created to reduce wear and costs. First papers (69), showed a 10 years implant survival very short (68,1%); but this papers showed results obtained with the first polyethylenes. Recent papers didn't highlight difference between metal and polyethilene (70-72). On the contrary Asiatic engineers and farmaceutic farms, tried to develop this plastic device to reduce costs.

Nowadays there aren't papers able to value which materials is better between polyethylene and metal. Highly cross-linked polyethylene, in fact, can guarantee a better anatomic congruence (73, 74), a major wear and oxidative resistance respect older materials (75, 76). A paper showed a similar survival (97% with a follow-up greater than 10 years) for all-poly design and metal-backed one (77). Other researches showed similar load tibial distribution in both designs (all-poly against metal-backed with a 10 mm or thicker poly bearing).

There are some papers against all-poly design (78, 79); those show a radiolucent line surrounding tibial components, that, if it's thicker than 2 mm, could consent a tibial loosening.

Moreover, in metal-backed design, it's possible using a modular tibial bearing, doing more conservative tibial cuts and in case of re-intervention, only bearing substitution it's less expansive, in term of costs and bone stock, than all-poly tibial one.

For these reasons many surgeons choose metal-backed design.

Some researchers, recently, studied a new solution: using pre-forming mould to stuff with plastic materials, to create prosthetic component (like in an antibiotical spacer). Research and development of this new devices could be onerous in term of times and costs, but using this new materials could decrease the costs of implantation in the future and could give us a valid option to traditional designs.

Design evolution, means, also, reducing friction and wear between component surfaces to increase implant survival and functionality. This regards surfaces lubrification (80). Fluid film lubrication will result in low friction, which could improve the kinematics and eliminate the 'stick periods' characteristic of metal on UHMWPE bearings. UHMWPE, have a coefficient of friction in the range 0.05–0.2. In addition, the surface wear should be significantly reduced (81). Attempts to achieve fluid film lubrication have been made using polyether ether ketone (PEEK) and, particularly, polyurethane materials, producing what has been termed 'cushion-form' or 'compliant-layer' bearings. In a series of analyses and experiments, measurements were made of the friction and the wear of a metal femoral component articulating on a polyurethane layer bonded to a rigid substrate. With the bearing operating in a mixed lubrication regime, the coefficient of friction was 0.001–0.02582,83. However, under more severe loading considerations, this value increased to 0.08–0.14, accompanied by small scratches and tears on the bearing surface. In simulator tests, dimples were produced in the bearing contact due to creep. For low-modulus material, fragmentation occurred, but no such problem or wear fragments were noted for higher modulus. However, debonding was still observed.

Further studies, focusing mainly on debonding, were carried out. Flat polyurethane layers with a thickness of 2 mm and 3 mm were tested, as well as contoured surfaces, as is usual in TKR. When different force combinations were investigated, the results were variable; some combinations resulted in some delamination, whereas others produced no damage. Taking all of the experiments together, it is evident that the advantages of low friction and wear are attainable.

However, further extensive work is indicated to demonstrate that the advantages apply under all feasible conditions of loads and motions, and likewise that the material and bonding are durable under these conditions. Probably in the future, it will possible to create the "perfect bearing" using polyethylene and polyurethane together.

Other researchers tried to find new solutions and new materials also for femoral and tibial component.

We talk about ceramics. Ceramics are crystalline solid chemical compounds with a high chemical covalent-ionic bonds. The most important ceramics are Alumina and Zirconia. Alumina, or aluminum oxide (Al2O3) was the ceramic forerunner and had been used for the first time in 1980 by Oonish (84) (cementless alumina femoral and tibial component, polyethylene bearing); this is a very hard, stable, and highly oxidized material, with a low coefficient of friction and low bending stress (85, 86), but exhibited low fracture, loosening and ditching toughness values, which are lower than those of the metals used in orthopedic surgery (87-89). In 1990's it started to use an alumina femoral component in association with a metal tibial plate, to reduce rate of loosenings and in 1993 it began to use cemented alumina.

Natural alumina evolution was zirconia, or Zirconium oxide (ZrO2), used since 2001 in TKA (KU type, Kyocera Corp, Japan), a double stronger material than alumina, but very chimicaly unstable (90, 91). The addition of stabilizing materials such as yttrium oxide (Y2O3), created yttrium-stabilized tetragonal zirconia (Y-TZP) (92). But Y-TZP, was, unstable if submitted to heavy weights, with water and with fairly low temperature (93-95).

Nowadays, there is a high-performance ceramic biocomposite material that combines the excellent material properties of alumina ceramics in terms of chemical stability, hydrothermal stability, biocompatibility and extremely low wear and of zirconia ceramics with its superior mechanical strength and fracture toughness: Biolox Delta (Lima-LTO and Ceram-Tec) (Fig. 2).

A Zirconia and Niobio alloy (Zr-2,5%Nb) is used to create Oxinium (Smith & Nephew for example), very biocompatible, with minimum biologic availability and electrocatalytic activity, high resistance coefficient for wear and friction (96, 97).

This new material showed more than twice as hard as CoCr on the articular surface (98, 99), equivalent device fatigue strength between the materials (100), less wear with OxZr compared with CoCr articulating on UMHWPE (counter face by 40%-90% depending on test conditions) (101).

Numerous papers studied ceramic designs: one of these, conduced with 218 patients, compared ceramic design (LFA-1 Kyocera) with traditional one (Kinemax How-Medica) (102); results was similar for two designs.

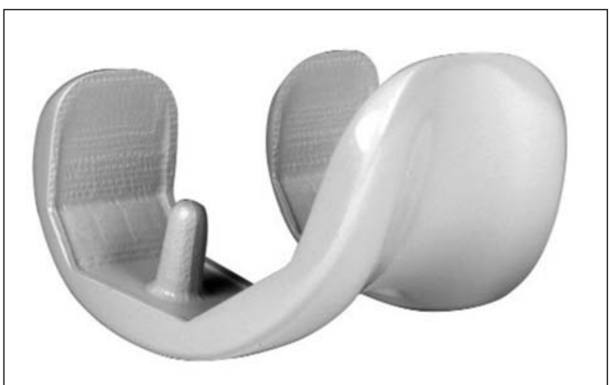

Figure 2. Biolox Delta

Another very recent paper (103), has been conduced on Bisurface prosthesis (Japan Medical Material), an "Hybrid design": ceramic femoral component and CoCrMo tibial component with UHWMPE bearing (follow-up 15 years).

Survival at 10 years was 95.9% and 94,3% at 15 years with a post-operative ROM 124°,2 ± 20°,8.

Limit of this model is production costs (104).

TKA evolution

With diagnostic and terapeutic evolution for OA treatment, that consent to postpone a surgical treatment, there are many new evolutions that consent to improve results in terms of quality and survival of products.

Together new prosthesis designs, was studied other devices and technologies.

Some researchers thought to introduce embedded sensors in the components to monitor such parameters as force, number of cycles of use, wear depth, signs of loosening, temperature, and so on. Data obtained are very helpful, but this technique is very expansive and it's difficult thinking to employ it if not in research centers.

The Unispacer was a contoured interpositional metal plate, although clinical results were not promising (105). A more recent concept of an early intervention treatment is the Arthrosurface device (Franklin, MA, USA), consisting of a domed metallic strip, fixed to the bone by in-setting and by ingrowth plugs. This component can be used independently, or in conjunction with a plastic tibial plug fitting in the area uncovered by the medial meniscus (106). The Orthoglide component (Advanced Biosurfaces Inc., Minnetonka, MN, USA) is a smooth metal interposition device which fits over the tibial surface.

A new approach is to project new designs based on imaging techniques data (CT, MRI, Fluoroscopy) processes with CAD-design technology (computational codes and computer aided design) (107). These data permit to individuate a series of clinical, radiographic, and biomarker parameters to project prosthetic components characterized by measures and conformations as much as possible congruents with knee anatomy of patient, able to obtain a better balance with capsular-ligament structures, to avoid components impeachment and to optimize bone resurfacing (108). With these procedures was projected a "shell-knee" design to substitute only cartilage damages area. Suddenly were created new designs to resurface the area of damage (iDuo Conformis, Burlington, MA, USA). A paper was conducted to project new designs based on 180 patients' MRI images, with their clinical and biomarker data. By means of 3D-doctor Software (Able Software corp, Lexington, MA, USA), it have been obtained 180 articulation profiles. Another software, Rapidform one (Inus Technoly, Seoul, South Chorea), suddenly, permitted to reproduce a complete (bone, menisci, cartilage layers and ligaments) solid knee models (109).

The distal medial femoral condyle showed the earliest loss, with posterior condylar thinning later still (Fig. 3). These data were confirmed if we'd examined intra-operative bioptic fragments

This experience consent to analyze biomarker data to prevent OA start and to slow down OA evolutions; at the same time, it consents creation of new personalized designs, with a better anatomical congruence and able to guarantee better results for prosthesic survival and functionality.

So imaging techniques, help us to recreate a knee as much as possible similar to pre-OA anatomical conformation.

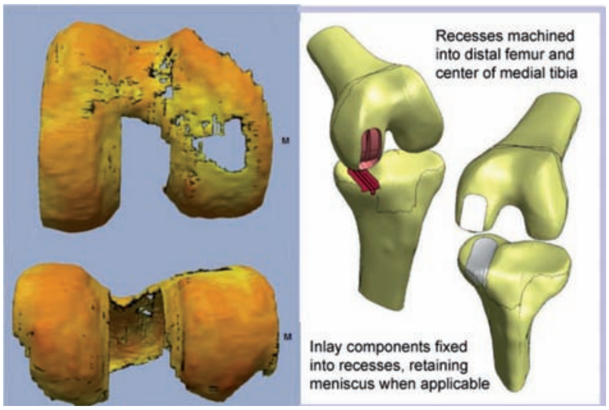

Figure 3. (Early OA Program director, Steven B. Abramson, MD, PhD, NYU-HJD)

In recent years, owing to the extensive data on TKA motion obtained using fluoroscopy, the goal that a TKA should reproduce 'normal knee kinematics' has often been expressed (Fig. 4).

These diagnostical techniques, moreover, have been permitted to individuate "critical points" in traditional TKA. Negative factors with present models have included:

- inadequate posterior displacement during flexion, which is one of the limiting factors in achieving high flexion (110, 111);
- reduced internal tibial rotation in flexion, with the same effect;
- excessive anterior sliding of the femoral component on the tibial component during flexion, called 'paradoxical motion'.

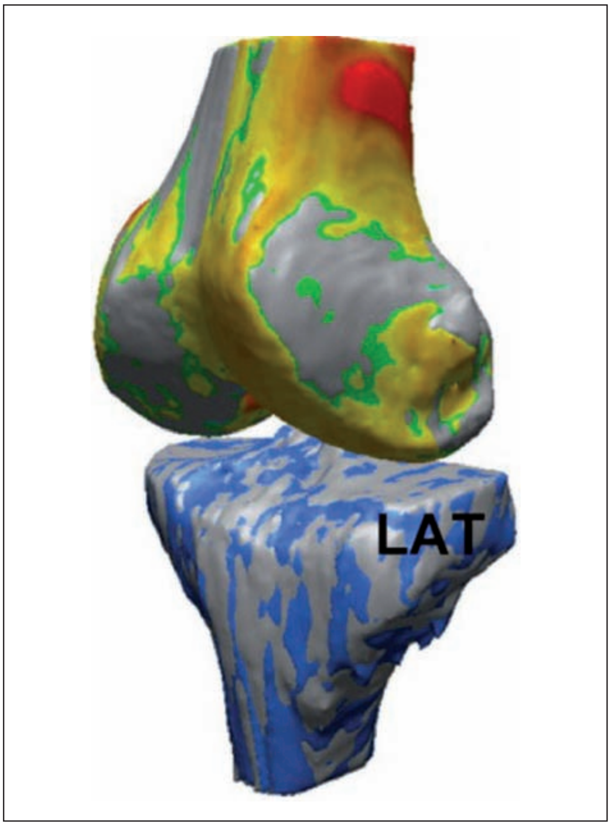

Figure 4. (Arno, S., Forman, R., Glassner, P., Regatte, R., and Walker, P. S. MRI analysis of anteroposterior stability in the normal human knee. In Proceedings of the IMechE Conference on Arthroplasty 2009: From Early Intervention to Revision, Lincoln's Inn Fields, London, 30 April–2 May 2009).In grey axial load, in blue posterior tibial shear force applied.

These factors may contribute to the reduced performance in high-demand activities and to the view of many patients that 'their knee does not feel normal" (112, 113).

Many kinematic studies of the normal knee have shown that there is limited anterior–posterior displacement on the medial side, in contrast to large displacements on the lateral side (Fig.4). This reinforces the principle that the knee achieves its anterior–posterior stability on the medial side, and its mobility on the lateral side: medial stability–lateral mobility.

Achieving this may be necessary if the knee is to feel 'normal' and function normally.

The mechanism proposed for the anterior–posterior medial stability involves the geometries and materials properties of the femoral and tibial condyles and the meniscus, under conditions of axial load. For small loads, the cruciate ligaments will be the primary anterior–posterior stabilizers, but as the axial load is increased, the condyles and meniscus will increasingly take over this role. This has implications for the design of the TKR.

The approach is to formulate designs where the joint components restore the mechanics of the bearing surfaces, the menisci, and the cruciate ligaments. To investigate designs that could potentially restore normal mechanics, some engineers in a paper (114) constructed an up-and-down crouching machine, based on the "Oxford test ring" concept (115) (Fig. 5).

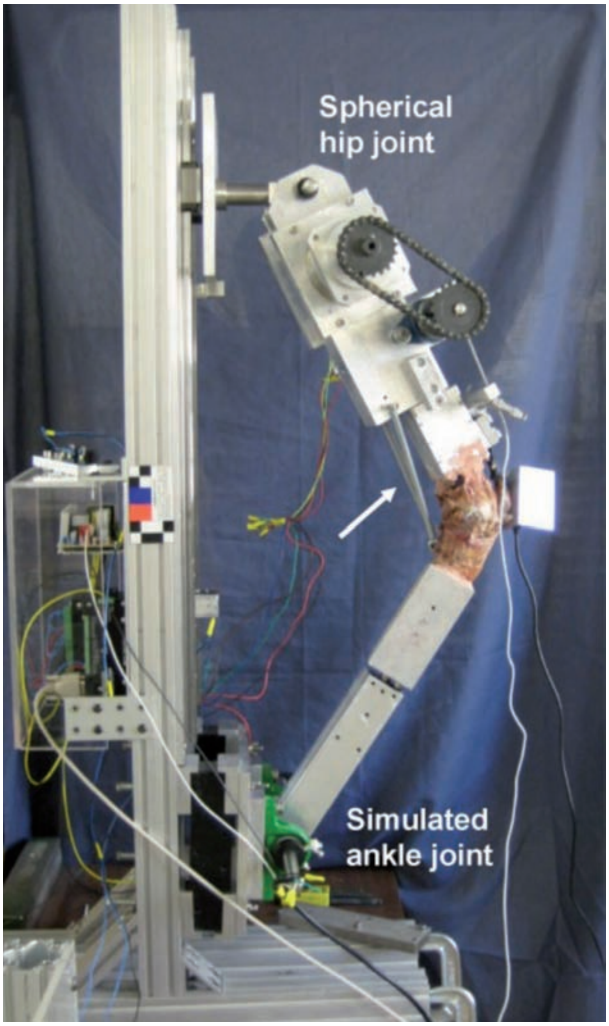

Figure 5. (Yildirim, G., Walker, P. S., and Boyer, J. Total knees designed for normal kinematics evaluated in an up-and-down crouching machine. J. Orthop. Res., 2009, 27(8), 1022–1027.)

This machine consents to imitate knee kinematic movements and to reproduce data obtained through a 3D equipment. Intact knee specimens were run first, monitoring the 3-D motion of the femur and tibia. The cartilage surfaces of the specimen were digitized to define reference axis for describing the motion. Different TKRs were designed in the computer, and stereolithographic (SLA) models were made in a tough low-friction plastic (Guided Motion Design or GM). These models were implanted in turn into the knee specimen and the 3-D motions were again measured.

There were obtained very interesting data: one of this was the "circular axis", an axis passing through centre of sagittal outlines of the posterior condyles (116). Guided motion designs were produced with enhanced medial anterior–posterior stability and increased lateral mobility, together with features to guide the knees into a normal neutral motion path. It was found that these designs reproduced much more closely the motion patterns of the anatomic knee, including avoidance of the paradoxical motion. GM-design circular axis was more closely to original knee than PS or Cr designs. These data, were reproduced through using desktop knee test machine (117); this equipment permits to apply torsional and compressive forces to the knees and to reproduce solid knee models.

The guided motion design displayed more normal medial behaviour, notably smaller anterior–posterior displacement and smaller laxities than PS and CR designs. In these models the laxity reduced considerably when an axial compressive force was applied across the knee (probably to the action of the medial meniscus and the shape of the tibial bearing surfaces).

These experiments demonstrated that reproducing at least some of the mechanical characteristics of the anatomic knee was possible with a TKR where both cruciates were resected.

Analogue results have been obtained with Kneesim software (118), based on the "oxford test ring" too; it's able to reproduce human activities as walking and crouching down.

Medial-pivot design

"Medial pivot" design, also called "medial rotation" design (119, 120), reproduces a ball in a socket, a joint able to consent a bigger ROM than traditional prosthesis. Many authors (121-124), showed that a normal knee consents a minimum movement of medial femoral condyle and a posterior translation of lateral femoral condyle, during flexion: this movement was called "medial pivot".

This prosthesis has been created to reproduce these characteristics. Medial condyle has a design with an identical curvature radius on the coronal and on the sagittal plane, to recreate a sphere; lateral condyle is smaller than medial with a cylindrical configuration, able to stabilize knee and to control rotation.

Moreover polyethylene bearing, is asymmetrical, with a high medial condyle congruence and a minor lateral one. These innovations consent a lateral consyle posterior sliding and rolling, while medial condyle works as a pivot during knee flexion and guarantees anterior-posterior stability like. Medial pivot design consents a better stability, a better ROM, a less wear stress on tibial surface and a longer polyethylene survival.

Many papers (125-127), showed that traditional models aren't able to reproduce, when implanted, roll-back why they were designed, but slide forward; this is called "paradoxical motion" and we've already described it. This phenomenon is reduced by medial pivot design, with a bigger stability (128, 129) and an important polyethylene wear reduction (130, 131). 228 patients treated with this prosthesis (1-13 years follow up) (132), reported only 2 loosening failures; none of patients had instability.

The other side of the coin, is that the notable medial congruence and, consequently, the load on articular surfaces, can reduce implant survival (133).

A further evolution regards tibial bearings. A recent paper (134), showed differences between two bearing designs, both used in medial pivot prosthesis: the original design (MP-design) and double-high design (DH-design). The difference between these two bearings is DH-design posterior profile, lower 3 mm than MP-design; this consent a bigger posterior slope. Slope consents to grow more marked knee flexion during femoral condyles roll-back on the bearing. This kind of articular geometry is one of the variables for knee flexion [other factors are soft tissues tension and PCL retention or sacrificing (135, 136)]. This paper studied 4 alternative designs: MP and DH-design with or without PCL retention. PCL retention consents in both design a bigger posterior translation; PCL sacrificing permits, instead, a better medial pivot movement. After all, paper doesn't show differences between these two designs; DH-design doesn't modify the ECPs (estimated contact points evaluated by means of CAD technology).

It isn't a medial pivot model, but as medial-pivot design, an experimental prosthesis (created by the Department of Mechanical Engineering in Taiwan), tried to reduce polyethylene wear with a new bearing and new condyle design (137) (Fig. 6).

To reduce debridement particles, produced by femoral sliding on bearing, has been created a new design in which bearing has a double bend radius, to guarantee on the one

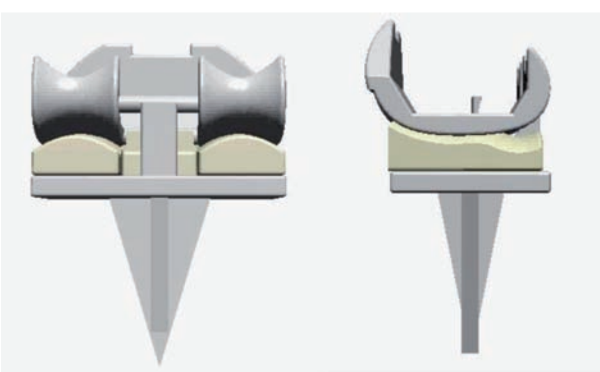

Figure 6. Yeh-Liang Hsu Yung-Chieh Hung Ju-Zhong Yin Design of a Novel Total Knee Prosthesis Using TRIZ Journal of Medical and Biological Engineering, 26(4): 177-185 2006

hand a bigger contact area between prosthetic component, on the other hand a smoother sliding between components. The bearing conformation, consents, moreover, an anterior-posterior sliding between femoral and tibial components.

As we said, this is an experimental design, not yet studied "in vivo"; therefore further studies will have to guarantee prosthetic effectiveness.

High flex design

Hi-Flex designs were introduced, to increase knee ROM; this prosthesistries to reach complete knee flexion by means of posterior rolling and translation (138). Traditional designs have a ROM limitation because of impingement between tibial and femoral surfaces. New Hi-Flex prosthetic designs, have an increased femoral condyles posterior offset. The tension of knee extensor apparatus, produced during flexion, reduces flexion in traditional design. Hi-Flex designs (Genesis II HI-Flex for example), have "deep flexion" bearings with modification in anterior, posterior and AP profiles. Anterior profile next to the patella, appears deeper than normal design, to avoid patellar tendon conflict and to reduce pain with reduction of the tension of the knee extensor apparatus; moreover this conformation, permits to minimize Hoffa's removal. Besides new bearings have a deeper posterior slope (5 degrees instead of 4 degrees) (139), this factor creates a PCL housing and prevents interferences between bearing and femoral component. At last, bearing deeper region is 1 mm in the back respect to the bearing midline; this improves knee flexion and reduces tissues tension.

Other Hi-Flex designs (Nex-Gen CR Flex), present some modifications on the femoral component; posterior condyle is thicker, to guarantee a higher contact with bone surface, at high flexion (155°); this contributes to the phisiological rolling-back movement. Moreover posterior condyle is 1,5 mm lower than traditional design, to minimize tissues tension on the lateral compartment during hyper-flexion; besides it has a reduction of medial-lateral dimension, to make easier intra-operative setting. At last, this design has a "minus size", thinner than 2 mm, on posterior condyle, than bigger size, to increase further knee flexion. Really, many papers conduct about these new designs, (Zimmer LPS and Zimmer LPS Hi-Flex; Genesis II PS insert and Genesis II HF insert have been compared), show that, there isn't a post-operative flexion increase, respect to traditional designs (140-144).

On average, Hi-Flex guarantees a flexion 2,1° better than traditional design (2°-4,3°); without a functional advantage for the patients

Gender Specifics TKA

There are three differences between these new designs and the traditional ones: a more oblique femoral groove, a thinner anterior profile and a narrower contour. These consent: to reduce friction between patella and prosthetic components; to eliminate the feeling of anterior "overstuffed" typical in women after TKR; at last to reduce resection bone.

Many papers were conduct to study these innovations (145-147); one of these, compared results reported by 85 women (some implanted traditional prosthesis, others gender specific one.

The paper highlighted analogue flexion values between these two design (125° and 126° respectively for traditional designs and for gender-specific ones); minimal flexion was about 90°. Patients satisfaction was similar too: 8,3 for gender-specific design and 8,1 for traditional one (range 0/10 complete discontent/ complete satisfaction).

Moreover, paper showed that traditional design consent to model femoral distal part better than gender-specific one. The last one, in fact, is smaller and expose more bone and this consent a bigger post-operative bleeding. The limit of these papers is a too much short follow-up (2 years); further researches need to obtain certain data.

Conclusions

As we told previously, we can say that better design for everyone, is the one that imitate own knee design. This means that, in the future the goal for scholars will be the achievement of the movement, rather than mechanical activity restoration. In fact, every patients, can feel as "abnormal" a knee mechanical activity, perfect but unable to reproduce own knee. New designs are trying to reproduce physiological anatomy of the knee and to create a design able to integrate with capsule-ligaments and muscle-tendons patient structures. Computer assistance is essential to reach these results: tanks to data obtained by means of CAD, in the future will be possible to obtain design suitable for every patient.

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